

Encouraging Accountability in Research: A Pilot Assessment of Training Efforts*

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The objective of this pilot assessment was to describe the response of a sample of grantee institutions to the federally-mandated training requirement in the responsible conduct of research that is part of NIH Training Grant (T32) funding. Materials collected by the Department of Health and Human Services (DHHS) were reviewed and described with the following five research goals:

- describe the target audience for training programs
- describe the locus of instructional responsibility for training programs
- describe whether all trainees at an institution participate in the same training program
- describe the program approaches, materials used and program contents
- create a source of baseline information for planning evaluations of future training programs
- identify areas for further research and analysis

Methods

The sample consisted of a collection of materials assembled by DHHS. These included syllabi, course outlines, case studies, reading lists, institutional research policies, and other information provided by training grant recipient institutions about their research ethics programs. In June 1996, the Office of Science Policy, Office of the Assistant Secretary for Planning and Evaluation, DHHS, sought to create “a library of course materials that are being used by T32 grantees.” A letter was sent to a stratified sample of T32 grantees requesting “any training materials currently used to instruct trainees in research integrity and misconduct” (1). The stated goal of collecting this library of information was to provide an understanding of training programs in the responsible conduct of research, including the range of institutional approaches for meeting the training grant requirement. This information was not collected as part of assessing regulatory compliance or as part of any oversight effort, but to create a resource and a source of baseline information for planning evaluations of future training programs (2).¹ This sample served as a convenient and best available sample for this review.

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DHHS contacted awardees at 50 of the 210 institutions that held training grants as of October 1995. (3) DHHS selected these 50 based on number of training grants, geographical location, status as public or private institution, and number of T32 trainees at the institution. For those institutions with multiple training grants, individual grants were selected for inclusion in the sample in order to obtain diverse representation. Selection factors included: the number of trainees, the distribution of pre- and post-doctoral students, and representation of clinical and basic research.

DHHS contacted Principal Investigators by telephone and follow-up letter, and requested that they provide “any training materials currently used to instruct trainees in research integrity and misconduct [including] materials such as the syllabi, course outlines, case studies, reading lists, institutional codes of conduct in research, etc., [and] any information [that] readily . . . describes the context in which such materials are introduced to students and the method of training” (4). Respondents from 45 of the 50 institutions contacted provided information concerning a total of 75 training grants.

Access to and copying of these publicly available materials was provided by the Office of Science Policy, Office of the Assistant Secretary for Planning and Evaluation, DHHS, in November 1996.

Approach

A coding form was developed as a method to collect and summarize information from the sample. Descriptive statistics were calculated using standard statistical software.

The characteristics of the sample were described at the level of either the institution ($n=45$), or the responsible conduct of research training program ($n=75$). In order to understand whether institutions shared characteristics based on number of training grants, the sample of institutions was stratified into thirds by number of training grants. For this purpose, these groupings were categorized as: “low-density” institutions (14/45 [31.1%] of the institutions) which held four or fewer training grants; “medium-density” institutions (15/45 [33.3%] of the institutions) which held from five through nine training grants; and, “high-density” institutions (16/45 [35.6%] of the institutions) which held ten or more training grants. Institutions also could have been grouped by

total number of trainees. In examining total number of trainees and number of T32s against other variables, each was found to be a proxy for the other. Variables, where appropriate, are grouped by numbers of T32s only.

Results

There were 45 institutions in the sample representing 660 T32s (number of T32s at each institution ranges from 1 to 60, with a median of 6) and 4,883 trainees (number of T32 trainees at each institution ranges from 3 to 507, with a median of 38). Responses concerning 75 training grants were represented in the sample.

Of the 45 institutions, 25 [55.6%] were public educational institutions, 17 [37.8%] were private educational institutions, and 3 [6.7%] were non-academic institutions (i.e., a professional organization, a non-profit service provider, and an independent research organization).

Institutional Characteristics

The sample was reviewed to determine the target audience for the training programs. Two-thirds of institutions represented in the sample required that only T32 trainees receive training in the responsible conduct of research. In this sample, this result was not affected by the number of training grants held by the institution: 9/14 [64.3%] of low-density, 10/15 [66.7%] of medium-density, and 11/16 [68.8%] of high-density institutions required training only for T32 trainees. Over one-quarter of all of the institutions, however, required much broader participation of either all trainees in the school or college, all graduate students or all trainees in the institution.

In half (23/45 [51.2%]) of the institutions represented in the sample, the responsibility for the responsible conduct of research training program was located at the departmental or Principal Investigator level. Another quarter located the responsibility at the institutional level. In the materials submitted, 4 [8.9%] of the institutions placed responsibility for the program in their ethics faculty. The institutions that placed responsibility for the program in their ethics faculty were among the highest-density institutions in the sample. They each had 18 or more training grants, and represented the top quarter of the sample by number of training grants. The majority of low-density and medium-density institutions had the locus of

program responsibility at the department level [64% and 66%, respectively], while the majority of high-density institutions had the locus of program responsibility above the department level [75%].

For those 41 institutions with more than one NIH training grant, 24 [58.5%] used the same responsible conduct of research program for all those required to receive training in the responsible conduct of research. As the number of training grants at an institution increased, the proportion of institutions utilizing the same responsible conduct of research training program decreased. Seven of the 10 [70%] low-density, 9 of the 15 [60%] medium-density, and 8 of the 16 [50%] high-density institutions used the same program for all trainees.

Program Characteristics

The material from the 45 institutions in the sample included information from 75 training grants. Depending on the characteristic being examined, the following analyses were based on either the number of institutions (n=45) or the number of programs (n=75). The denominator is noted in each case.

Program approach

Submitted materials indicated that one-quarter of the programs specifically tailored training to the trainee population, with either discipline-specific focus or both general and discipline-specific material.

Of the 45 institutions, 28 [62.2%] had a formal course in place to satisfy the training grant requirement. A greater proportion of medium-density and high-density institutions utilized a formal course than did low-density institutions: 5 of the 14 [35.7%] low-density institutions, 13 of the 15 [86.6%] medium-density institutions, and 10 of the 16 [62.5%] high-density institutions had a formal training course in place.

Fourteen [31.1%] of the institutions represented in the sample had programs that indicated the availability of ethics training that could be taken to supplement the course or training offered to satisfy the training grant requirement.

Only two institutions indicated that formal training was provided to faculty who then carried out the required responsible conduct of research training—a “train the trainer” approach. These

two institutions were among the highest-density institutions.

Lecture was the most popular method of instruction represented in the sample (53/75 [70.7%]). (Table I) To examine whether programs relied solely on lectures to satisfy the requirement, the frequency of lecture format in combination with other methods of instruction was determined. (Table II) For those programs that used lectures as a method of instruction, only a small proportion (4/53 [7.5%]) did not supplement lectures with some less didactic method or methods of instruction that provide opportunities for greater interaction. It is interesting to note that the materials indicated that there was very little use of “brown bag” discussions to satisfy the requirement.

Contact hours could be determined for 42 of the 75 [56%] programs for which information was received. The median number of contact hours for these programs was 10 hours. The range was from 4 to 72 contact hours.

Method of Instruction*	# [%]
Lecture	53 [70.7]
Case study	42 [56.0]
Small group	36 [48.0]
Seminar	21 [28.0]
Student presentation	11 [14.7]
Mentor	9 [12.0]
Brown bag	1 [1.3]
Computer	0 [0]

Table 1. Method of program instruction. n=75
* programs could have more than one method of instruction

Methods of Instruction	# [%]
Lecture only	4 [7.5]
Lecture + seminar	3 [5.7]
Lecture + small group	11 [20.8]
Lecture + case studies	16 [30.2]
Lecture + small group + case studies	14 [26.4]
Lecture + seminar + small group	3 [5.7]
Lecture + seminar + small group + case studies	1 [1.9]
Lecture + brown bag + small group	1 [1.9]

Table 2. Combination of methods of program instruction with lectures. Fifty-three programs used lecture as part of their instructional format. n= 53

Program Contents

Material from the 75 training grants was reviewed to determine whether course content included the five topic areas recommended by NIH in the NRSA policy—conflict of interest, responsible authorship (including issues of peer-review, plagiarism, and research reporting), policies for handling misconduct (including institutional policies, federal policies, whistleblowing and reporting misconduct), policies regarding the use of human and animal subjects, and data management (including fabrication, falsification, handling research data, materials and information, and data and objectivity).

Fifty-one [68%] of the T32 programs covered four or five of the NIH recommended program content areas while 24 [32%] of the T32 programs covered three or fewer of the categories. The top five ranked categories fell within the five NIH recommended program content areas, and the top ten ranked categories were addressed by at least half of the T32 programs. (Table 3)

Content issues that were identified by fewer than half the programs include:

- whistleblowing and reporting misconduct (22 of 75 programs)
- the more theoretical issues encompassed in a category we labeled “moral reasoning” (21 of 75 programs)
- social issues encompassed in a category we labeled “science and society” (10 of 75 programs)
- development of certain skills necessary for becoming a productive scientist, e.g. grants preparation and funding, job hunting, oral communication, tenure, teaching, etc., (3 to 15 programs).

General skills related to publishing and writing received greater attention, with 38 and 44 programs addressing them, respectively.

Rank	Content Area	# [%]
1	Authorship	65 [86.7]
2	Data Management	56 [74.7]
3	Human Subjects	53 [70.7]
4	Animal Use	51 [68.0]
5	Conflict of Interest	49 [65.3]
6	Institutional Policy	45 [60.0]
7	Skills-Writing	44 [58.7]
7	Confidentiality	44 [58.7]
9	Skills-Publishing	38 [50.7]
10	Intellectual Property	37 [49.3]
11	Mentor/Mentee	35 [46.7]
12	Information Sharing	24 [32.0]
13	Whistleblowing and Reporting Misconduct	22 [29.3]
14	Moral Reasoning	21 [28.0]
15	Other Content	20 [26.7]
16	Federal Policies	16 [21.3]
16	Grants Management	16 [21.3]
18	Skills-Grant Preparation	15 [20.0]
19	Organizational Structure	14 [18.7]
20	Skills-Oral Presentation	11 [14.7]
21	Science and Society	10 [13.3]
22	Laboratory Safety	9 [12.0]
23	Skills-Teaching	6 [8.0]
24	Skills-Tenure	4 [5.3]
24	Skills-Funding	4 [5.3]
26	Skills-Jobs	3 [4.0]

Table 3. Ranking of program content areas. N = 75; programs can have more than one content category.

Thirty-six of the 75 [48%] programs provided syllabi or other similar program materials in the information sent in response to the DHHS request. Of those, 6 [16.7%] identified goals and objectives for the responsible conduct of research training program. Based on this limited information, few programs set forth traditional goals and objectives for their educational efforts.

Training Materials

The information submitted was reviewed to identify the most frequently noted training materials used by programs. The top three referenced training materials were: 1) institutional policies concerning the responsible conduct of research (45/75 [60%]); 2) Korenman et al., *Teaching the Responsible Conduct of Research through a Case Study Approach: A Handbook for Instructors* (5) (30/75 [40%]); and, 3) the National Academy of Science’s *On Being a Scientist* (6) (24/75 [32%]). While the institutional policies are specific to

each institution, Korenman et al. (5) and NAS (6) are prepared and widely distributed by professional societies. Of the materials referenced in the sample, the following four each are marketed as offering complete training materials in the responsible conduct of research without need to supplement: Korenman et al. (5); Macrina, *Scientific Integrity: An Introductory Text with Cases* (7); the American Association for the Advancement of Science's *Integrity in Scientific Research: Five Video Vignettes* (8); and Bulger et al., *The Ethical Dimensions of the Biological Sciences*. (9) Forty-three [57.3%] of the programs used one or more of these four materials. A greater proportion of high-density institutions (12/16 [75%]) used at least one of these four "ready-to-use" training materials, than did low- or medium-density institutions (7/14 [50%]; and 7/15 [46.6%] respectively).

Discussion

In this sample, training in the responsible conduct of research in response to the NIH requirement was most often directed at T32 trainees. While the NIH policy encourages expanding training to others, it requires that only T32 trainees receive such training. If this result is representative of institutional commitment to training in the responsible conduct of research, future scientists' exposure to responsible conduct of research will largely depend on their source of funding. The characteristics of the minority of institutions that make a broader commitment to responsible conduct of research education and training for its trainees deserve further exploration.

The T32 recipient institutions in the sample employed a diversity of approaches to satisfying the training grant requirement. Approaches varied both among and within institutions. Further, the number of T32s held at the institution had some impact on how the training grant requirement was met.

Locating program responsibility at the departmental or Principal Investigator level, as did about half of the institutions in the sample, may offer ethics training that is more tailored to the trainees' disciplines. In the materials reviewed, a quarter of the programs offered some discipline-specific training. Further research is necessary to determine whether a relationship exists between discipline-specific training and location of program responsibility within an institution.

The finding that a greater proportion of high-density institutions placed program responsibility above the departmental level may indicate that as institutional demand for responsible conduct of research training programs increases, more shared institutional resources are sought. However, based on T32 density, those institutions with the highest density had the smallest proportion that utilized the same responsible conduct of research training program for all trainees. This finding may be attributable to more diverse training programs for which different approaches are used, even if some institutional resources are shared. Perhaps the administrative level at which the ethics training decision is made affects the institutional approach. Future research might focus on examining this question, and the sharing of institutional resources regardless of any differences in program approach.

The small number of institutions that placed responsibility for teaching in their ethics faculty may be a reflection of the fact that institutions with greater numbers of training grants are more likely to have ethics faculty—it would be interesting to compare the characteristics of institutions that have ethics faculty and place program responsibility in them.

Contrary to the expectations of the authors, lecture format alone was rarely used; nearly two-thirds of the programs employed lectures plus additional instructional approaches. Also contrary to popular belief among teachers of responsible conduct of research, brown bag discussions were rarely identified as an approach used to satisfy the training grant requirement. The wide range of contact hours offered by programs underscores the great diversity in the implementation of the requirement.

The majority of programs (51/75 [68%]) specifically addressed four or five of the NIH-recommended subject categories. Either the recommendations in the NIH policy have influenced program content or the subject categories are well-chosen and represent the commonly accepted basic issues in the responsible conduct of research.

Some variation in the subject matter covered by programs may result from differences in the needs of trainees in basic versus clinical research. However, four of the five NIH-recommended categories are relevant to all scientific research, i.e., one category, human and animal research issues, may not be relevant to all researchers.

Therefore, one would expect a higher proportion of programs than was observed to address at least four of the categories.

Most educational efforts in other areas typically identify goals and learning objectives as a way of focusing teaching approaches and assessing their success. In this sample, few of the T32 programs (6/36) identified goals and objectives. This would seem to imply that programs do not approach training in the same manner they would typically approach other educational efforts.

“Ready made” materials and materials sanctioned and made available by professional organizations were a popular source of training materials. This underscores the need to ensure that these materials, which are so heavily relied upon, are of high quality, complete, appropriately tailored for the target audiences, and widely available.

The most popularly used material, institutional ethics policies, is critical for trainees’ basic understanding of responsible conduct of research. The proportion in the sample who used these policies as a educational tool could be viewed as unexpectedly low (45/75 [60%]).

Future Research

In addition to the findings discussed, this review indicates the need for further research on institutional approaches to education and training in the responsible conduct of research. First, additional research is needed on the characteristics of training programs. A description of primary and participating instructors in training would be instructive, particularly knowing the extent to which an institution’s ethics faculty are involved in program development, administration and teaching. In addition, it would be useful to understand the differences in approach and content of training provided for trainees in different disciplines, particularly in the clinical sciences as compared to the basic sciences. This information would point to differences in the perceived needs for subgroups of trainees, and could aid development of appropriate materials and programs, for example, the use of core programs with tailored components.

Second, research is needed on the effectiveness of training initiatives. Evaluation of a variety of programs and their approaches would be particularly useful. Some target areas for

program evaluation include:

- the use of a core program plus tailored discipline- and skill-specific components
- resource utilization-sharing by multiple programs within and among institutions
- skill-based training programs, with assessment of trainee competencies
- the importance of goals and objectives of programs as away to focus the educational effort
- resource needs for “train the trainer” approaches
- the effectiveness of stand-alone training materials
- the effectiveness of one-day programs compared to series of sessions

There is also a need to identify how to broaden current training efforts to ensure that all scientists-in-training are prepared to address ethical dilemmas in their professional careers, regardless of the source of funding for their training. Such initiatives might include education of institutional administrators about the importance of responsible conduct of research training beyond T32 trainees and the enlisting of institutional commitments for broadened training efforts. In addition, there is a need for improved dissemination of effective approaches to responsible conduct of research training in the relevant professional literature.

The results of this review should not be viewed as representative of responses to the NIH mandate at either the programmatic or institutional level because of the sample’s limitations. The way the sample was selected and the generality of the government’s request for materials may have had some impact on the results. Since the materials were collected independently from this review, a targeted questionnaire would provide more detailed information. However, the results of this review are a valuable first step in describing how institutions and investigators meet the mandate for training in responsible conduct of research

Conclusion

The intent of this pilot assessment was to describe for the first time how institutions and investigators are responding to the NIH mandate for training in the responsible conduct of research that is part of NIH Training Grant (T32) funding. The results provide a snapshot of the variety of

approaches used in programs across the country.

Understanding the range of approaches taken in the education and training in the responsible conduct of research is a crucial part of any effort to encourage accountability in research, on the part of trainees, researchers, institutions, and funders. Those engaged in training and education can gain important insights for further study given the diversity of approaches seen in this review, while at the same time pointing to the need for some consistency of training content. Further, education and training in the responsible conduct of research should be part of all the training of all scientists and not a function of the source of funding for training. Only by assuring the highest standard of research conduct, can we be confident that the trust the American people continue to place in biomedical research is truly deserved.

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Notes

1. DHHS staff selected this approach to the collection of resources because their primary purpose was to gain insights into the scope and character of the materials being used to teach responsible conduct of research, and in a way that minimized the reporting burden for the cooperating institutions. They recognized from the outset that this approach would enable only qualitative characterization at best, and unlike a formal survey, would not yield readily analyzable data. (DHHS, 1997)

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